PC Rev'd
09-29-05

FEE

DATE OUT: 29 Sept 2005

SUBJECT: **EP [x] MP [ ] PRODUCT CHEMISTRY REVIEW**
DP BARCODE No.: D313922
REG./File Symbol No.: 264-IUL
PRODUCT NAME: Asulox XP Herbicide
COMPANY: Bayer CropScience LP
FOOD USE: [x] **PC CODE:** 106902
Decision No. 353690 **Integrated Formulation [ ]**

TO: RM #23, Joanne Miller/Eugene Wilson
Herbicide Branch
Registration Division (7505C)

FROM: Bruce F. Kitchens, Chemist
Technical Review Branch
Registration Division (7505C)

Bruce F. Kitchens
29 Sept 2005
101505

INTRODUCTION:

The registrant, Bayer CropScience LP, is submitting an application for the registration of the new end-use product, Asulox XP Herbicide. The active ingredient in this product is the Sodium salt of Asulam (88.6% a.i.) at a label nominal concentration of 34.3% a.i. This product is intended for use as an herbicide. In support of this request, the registrant has submitted a basic Confidential Statement of Formula (CSF) dated 06 Jan 2005, a draft label, and product chemistry data contained in MRID# 464677-01. During the course of this review, the registrant submitted a revised basic CSF dated 22 Aug 2005 to correct several deficiences. The Technical Review Branch (TRB) has been asked to review this submission.

SUMMARY OF FINDINGS:

TRB has reviewed this submission and reports the following findings:

1. This product is produced from a registered source of the active ingredient.

2. All inert ingredients are cleared for use in formulated pesticide products. In addition, all inert ingredients are exempt from the requirement of a food tolerance.

3. The nominal concentration of the active ingredient listed on the proposed basic CSF and the draft label are the same.

4. The draft label contains the appropriate storage and disposal statements.

5. The active ingredients certified limits as proposed on the basic CSF are acceptable.

CONCLUSIONS:

TRB has reviewed this submission and concludes the following:

1. The basic formula CSF for the proposed end-use product, Asulox XP Herbicide dated 22 Aug 2005 is acceptable.

2. This submission satisfies the data requirements as specified in 40 CFR 158.155, 158.160, 158.165, 158.167, 158.175, and 158.180 with respect to product identity and composition, description of materials used to produce the product, description of formulation process, discussion of formation of impurities, certified limits, and enforcement analytical method.

3. This submission satisfies the data requirements as specified in 40 CFR 158.190 with respect to physical and chemical properties.

   The data requirements for storage stability and corrosion characteristics are not satisfied at this time. The registrant indicates that one-year studies are in progress and will be submitted to the Agency upon completion.

PRODUCT CHEMISTRY DATA (GROUP A)

21. Chemical IDs/Manufacture/ Analytical Information	Data Required Fulfilled	MRID No.
830-1550 Product Identity and Composition	Y	464677-01
830-1600 Description of Materials Used to Produce the Product	Y	464677-01
830-1620 Description of Production Process	NA	
830-1650 Description of Formulation Process	Y	464677-01
830-1670 Discussion of Impurities	Y	464677-01
830-1700 Preliminary Analysis	NA	
830-1750 Certified Limits	Y	464677-01
830-1800 Enforcement Analytical Method	Y	464677-01

PRODUCT CHEMISTRY DATA (GROUP B)

Physical/Chemical Properties	Data Required Fulfilled	Value or Qualitative Description	MRID No.
830-6302 Color	Y	Tea brown	464677-01
830-6303 Physical State	Y	Liquid	464677-01
830-6304 Odor	NR		
830-6314 Oxidation/Reduction:Chemical Incompatability	NA	Product does not contain oxidizing or reducing agents	
830-6315 Flammability/Flame Extension	Y	Flash point: 200°C	464677-01
830-6316 Explodability	NA	Product does not contain explosive components	
830-6317 Storage Stability of Product	I	Study in progress	
830-6319 Miscibility	NA	Product not an EC or diluted with petroleum solvents	
830-6320 Corrosion Characteristics	I	Study in progress	
830-6321 Dielectric Breakdown Constant	NA	Product not used around electrical equipment	
830-7000 pH	Y	8.05	464677-01
830-7100 Viscosity	Y	7 cps (5-10 cps)	464677-01
830-7300 Density	Y	10 lbs/gal	464677-01

Explanations: Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.

Enforcement analytical method: (MRID No. 464677-01)

The active ingredient, Asulam was determined by High Performance Liquid Chromatography (HPLC) using Ultra-Violet (UV) detection at 254 nm. Dimethylphthalate is used as the internal standard by Analytical method AM001804KF2. Method was validated for precision, linearity, accuracy, and specificity.

Equipment and Parameters

HPLC: Agilent Model 1100
Detector: Ultra-Violet (UV)
Wavelength: 254 nm
Integrator: Agilent Chemstation
Column: Agilent 250mm x 4.6 mm id Rx-C18, Agilent #880967-902
Size of sample: 5.0 µL
Mobile Phase: A: Water, 0.1% H_3PO_4
B: ACN

Solvent Program:

Time (min)	%B
Initial	20
10	50
12	50
13	20

Flow rate: 1.2 ml/min.
Duration of time: 15 minutes